



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/475,822	06/07/1995	MARC ALIZON	3495.0010-24	4214
22852	7590	02/13/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/475,822	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 35-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 35-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.129(a)

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on November 19, 2003 has been entered.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires that when new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Here, two claims are numbered "41".

Misnumbered claim 41 been renumbered 42. Specifically, the second claim "41", drawn to the kit of claim 41, was renumbered 42.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 35, 37, 39, 41, 43 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 4000 and 9000 are presented below.

```
Query: 4010 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4069
          ||||||| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
Sbjct: 4197 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4256
pol    856   I   P   Y   N   P   Q   S   Q   G   V   V   E   S   M   N   K   E   L   K   K
```

Query: 4070 ttataggacaggtaagagatcaggctgaacatcttaagacacgcgtacaaatggcagtat 4129

Art Unit: 1634

Sbjct: 4257 ttataggccaggtaagagatcaggctgaacatcttaagacagcagtacaatggcagtat 4316
pol 876 I I G Q V R D Q A E H L K T A V Q M A V

Query: 4130 tcatccacaattttaaaagaaaannnnnnnnnnntacagtgcagggaaagaatag 4189
Sbjct: 4317 tcatccacaattttaaaagaaaaggggggattgggggtacagtgcagggaaagaatag 4376
pol 896 F I H N F K R K G G I G G Y S A G E R I

Query: 4190 tagacataatagcaacagacatacaaactaaagaattacaaaaacaattacaaaaattc 4249
Sbjct: 4377 tagacataatagcaacagacatacaaactaaagaattacaaaaacaattacaaaaattc 4436
pol 916 V D I I A T D I Q T K E L Q K Q I T K I

Query: 4250 aaaatttcgggatttacaggcacgcagaaatccactttggaaaggaccagcaaagc 4309
Sbjct: 4437 aaaatttcgggatttacaggcacgcagagatccactttggaaaggaccagcaaagc 4496
pol 936 Q N F R V Y Y R D S R D P L W K G P A K

Query: 4310 tcctctggaaaggtaagggcagtagtaatacagataatgtgacataaaagtagtgc 4369
Sbjct: 4497 tcctctggaaaggtaagggcagtagtaatacagataatgtgacataaaagtagtgc 4556
pol 956 L L W K G E G A V V I Q D N S D I K V V

Query: 4370 caagaagaaaagcaaagatcattaggattatggaaaacagatggcaggtgatgttg 4429
Sbjct: 4557 caagaagaaaagcaaagatcattaggattatggaaaacagatggcaggtgatgttg 4616
pol 976 P R R K A K I I R D Y G K Q M A G D D C

Query: 4430 tggcaagttagacaggatgaggattagaacatggaaaagtttagtaaaacaccatatgtat 4489
Sbjct: 4617 tggcaagttagacaggatgaggattagaacatggaaaagtttagtaaaacaccatatgtat 4676
pol 996 V A S R Q D E D ^^^

Query: 4490 gttcaggaaagctagggatggtttatagacatcactatgaaagccctcatccaaga 4549
Sbjct: 4677 gttcaggaaagctagggatggtttatagacatcactatgaaagccctcatccaaga 4736

Query: 4550 ataagttcagaagtacacatcccactagggatgctagattgtaataacaacatattgg 4609
Sbjct: 4737 ataagttcagaagtacacatcccactagggatgctagattgtaataacaacatattgg 4796

Query: 4610 ggtctgcatacaggagaaagagactggcattgggtcaggagtcctccatagaatggagg 4669
Sbjct: 4797 ggtctgcatacaggagaaagagactggcattgggtcaggagtcctccatagaatggagg 4856

Art Unit: 1634

Sbjct: 5456 taaaaagtgtgcttcattgccaagttgttcacaacaaaagccttaggcatctccta 5515
orfQ 1 C Q V C F T T K A L G I S Y

Query: 5330 tggcaggaagaagcggagacagcgacgaagacccctcaaggcagtcatcaagt 5389
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5516 tggcannaagaagcggagacagcgacgaagacccctcaaggcagtcatcaagt 5575
orfQ 15 G X K K R R Q R R P P Q G S Q T H Q V

Query: 5390 ttctcttatcaaagcagtaagtagtacatgtaatgcaacctatacaaatacgatgc 5449
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||

Sbjct: 5576 ttctcttatcaaagcagtaagtagtacatgtaatgcaacctatacaaatacgatgc 5635
orfQ 35 S L S K Q ^^^

Query: 5450 attagtagtagcaataataatagcaatagttgtgtggccatagtaatcatagaatata 5509
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5636 attagtagtagcaataataatagcaatagttgtgtggccatagtaatcatagaatata 5695

Query: 5510 gaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaaagcaga 5569
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5696 gaaaatattaagacaaagaaaaatagacaggttaattgatagactaatagaaagcaga 5755
env 1 K E Q

Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||

Sbjct: 5756 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggaaat 5815
env 4 K T V A M R V K E K Y Q H L W R W G W K

Query: 5630 ggggcaccatgctccttggatgttgcattgtgtgtacagaaaaattgtgggtca 5689
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5816 ggggcaccatgctccttggatattgtgcattgtgtgtacagaaaaattgtgggtca 5875
env 24 W G T M L L G I L M I C S A T E K L W V

Query: 5690 cagtcattatgggtacctgtgtggaaaggcaaccaccactctatttgcatcag 5749
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5876 cagtcattatgggtacctgtgtggaaaggcaaccaccactctatttgcatcag 5935
env 44 T V Y Y G V P V W K E A T T T L F C A S

Query: 5750 atgctaaagcatatgatacagaggtacataatgtttggccacacatgcctgttaccca 5809
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5936 atgctaaagcatatgatacagaggtacataatgtttggccacacatgcctgttaccca 5995
env 64 D A K A Y D T E V H N V W A T H A C V P

Query: 5810 cagaccccaacccacaagaaggtagtattggtaatgtgacagaaaatttaacatgtgga 5869
||||||| ||||||| ||||||| ||||||| ||||||| ||||||| ||||||| |||||||

Sbjct: 5996 cagaccccaacccacaagaaggtagtattggtaatgtgacagaaaatttaacatgtgga 6055

Art Unit: 1634

env 84 T D P N P Q E V V L V N V T E N F N M W

Query: 5870 aaaatgacatggtagaaacagatgcatgaggatataatcagttatggatcaaagcctaa 5929

|||||||

Sbjct: 6056 aaaatgacatggtagaaacagatgcatgaggatataatcagttatggatcaaagcctaa 6115

env 104 K N D M V E Q M H E D I I S L W D Q S L

Query: 5930 agccatgtgtaaaattaaccccactctgtgttagttaaagtgcactgattgaagaatg 5989

|||||||

Sbjct: 6116 agccatgtgtaaaattaaccccactctgtgttagttaaagtgcactgattgggaatg 6175

env 124 K P C V K L T P L C V S L K C T D L G N

Query: 5994 taataccaatagtagtagcgggagaatgataatggagaaaggagagataaaaaactgctc 6053

|||||||

Sbjct: 6195 taataccaatagtagtagcgggaaatgatgatggagaaaggagagataaaaaactgctc 6254

env 151 N T N S S S G E M M M E K G E I K N C S

Query: 6054 tttcaatatcagcacaaggataagaggtaaggcagaaagaatatgcannnnnnataa 6113

|||||||

Sbjct: 6255 tttcaatatcagcacaaggataagaggtaaggcagaaagaatatgcatttttataa 6314

env 171 F N I S T S I R G K V Q K E Y A F F Y K

Query: 6114 acttgatataatccaatagataatgatactaccagctatacgttacaagtttaacac 6173

|||||||

Sbjct: 6315 acttgatataatccaatagataatgatactaccagctatacgttacaagtttaacac 6374

env 191 L D I I P I D N D T T S Y T L T S C N T

Query: 6174 ctcagtcattacacaggcgtccaaaggatccttgagccaattccatacattattg 6233

|||||||

Sbjct: 6375 ctcagtcattacacaggcgtccaaaggatccttgagccaattccatacattattg 6434

env 211 S V I T Q A C P K V S F E P I P I H Y C

Query: 6234 tgccccggctggtttgcgattctaaaatgtataataagacgttcaatggAACAGGACC 6293

|||||||

Sbjct: 6435 tgccccggctggtttgcgattctaaaatgtataataagacgttcaatggAACAGGACC 6494

env 231 A P A G F A I L K C N N K T F N G T G P

Query: 6294 atgtacaaaatgtcagcacagtacaatgtacacatggaaattaggccagtagtatcaactca 6353

|||||||

Sbjct: 6495 atgtacaaaatgtcagcacagtacaatgtacacatggaaattaggccagtagtatcaactca 6554

env 251 C T N V S T V Q C T H G I R P V V S T Q

Query: 6354 actgctgttaaatggcagtctggcagaagaagaggtagtaattagatctgccaatttcac 6413

|||||||

Art Unit: 1634

Sbjct: 6555 actgctgttgaatggcagtctagcagaagaagaggttagtaattagatctgccaatttcac 6614
env 271 L L L N G S L A E E E V V I R S A N F T

Query: 6414 agacaatgctaaaaccataatagtagcagctgaaccaatctgttagaaattaattgtacaag 6473
|||||||

Sbjct: 6615 agacaatgctaaaaccataatagtagcagctgaaccaatctgttagaaattaattgtacaag 6674
env 291 D N A K T I I V Q L N Q S V E I N C T R

Query: 6474 acccaacaacaatacaagaaaaaagtatccgtatccagagaggaccaggagagcattgt 6533
|||||||

Sbjct: 6675 acccaacaacaatacaagaaaaaagtatccgtatccagagaggaccaggagagcattgt 6734
env 311 P N N N T R K S I R I Q R G P G R A F V

Query: 6534 tacaataggaaaaatagggaaatatgagacaaggcacattgttaacatttagtagagcaaaatg 6593
|||||||

Sbjct: 6735 tacaataggaaaaatagggaaatatgagacaaggcacattgttaacatttagtagagcaaaatg 6794
env 331 T I G K I G N M R Q A H C N I S R A K W

Query: 6594 gaataacactttaaacagatagatagcaaattaagagaacaatttggaaataataaaac 6653
|||

Sbjct: 6795 gaatgccactttaaacagatagctagcaaattaagagaacaatttggaaataataaaac 6854
env 351 N A T L K Q I A S K L R E Q F G N N K T

Query: 6654 aataatcttaagcagtccctcaggagggaccaggaaattgttaacgcacagtttaattg 6713
|||||||

Sbjct: 6855 aataatcttaagcaatccctcaggagggaccaggaaattgttaacgcacagtttaattg 6914
env 371 I I F K Q S S G G D P E I V T H S F N C

Query: 6714 tggaggggaattttctactgttaattcaacacaactgtttaatagtacttggttaatag 6773
|||||||

Sbjct: 6915 tggaggggaattttctactgttaattcaacacaactgtttaatagtacttggttaatag 6974
env 391 G G E F F Y C N S T Q L F N S T W F N S

Query: 6774 tacttggagtactaaagggtcaaataacactgaaggaagtgcacacaatccccatg 6833
|||||||

Sbjct: 6975 tacttggagtactgaagggtcaaataacactgaaggaagtgcacacaatcacactcccattg 7034
env 411 T W S T E G S N N T E G S D T I T L P C

Query: 6834 cagaataaaacaattataaacatgtggcaggaagttagggaaagcaatgtatccccatc 6893
|||||||

Sbjct: 7035 cagaataaaacaattataaacatgtggcaggaagttagggaaagcaatgtatccccatc 7094
env 431 R I K Q F I N M W Q E V G K A M Y A P P

Query: 6894 catcagtggacaaatttagatgttcatcaaattacaggctgttataacaagagatgg 6953
|||||||

Art Unit: 1634

Sbjct: 7095 catcagcgacaaatttagatgttcatcaaattttacaggcgttattacaagaagatgg 7154
env 451 I S G Q I R C S S N I T G L L L T R D G

Query: 6954 tggtaatagcaacaatgagtccgagatcttcagacctggaggaggatatgagggacaa 7013
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7155 tggtaataacaacaatgggtccgagatcttcagacctggaggaggatatgagggacaa 7214
env 471 G N N N N G S E I F R P G G G D M R D N

Query: 7014 ttggagaagtgaatttatataatataaagttagtaaaaattgaaccattaggatgcacc 7073
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7215 ttggagaagtgaatttatataatataaagttagtaaaaattgaaccattaggatgcacc 7274
env 491 W R S E L Y K Y K V V K I E P L G V A P

Query: 7074 caccaaggcaaagagaagagtggcagagagaaaaagagcagtggaaataggagcttt 7133
||||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7275 caccaaggcaaagagaagagtggcagagagaaaaagagcagtggaaataggagcttt 7334
env 511 T K A K R R V V Q R E K R A V G I G A L

Query: 7134 gttccttgggttcttggagcagcaggaagcactatggcgcagcgtcaatgacgctgac 7193
||||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7335 gttccttgggttcttggagcagcaggaagcactatggcgcacggtcaatgacgctgac 7394
env 531 F L G F L G A A G S T M G A R S M T L T

Query: 7194 ggtacaggccagacaattattgtcttgtatagtgcagcagcagaacaatttgctgaggc 7253
||||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7395 ggtacaggccagacaattattgtcttgtatagtgcagcagcagaacaatttgctgaggc 7454
env 551 V Q A R Q L L S G I V Q Q Q N N L L R A

Query: 7254 tattgaggcgcaacagcatctgttcaactcacagtctggggatcaagcagctccaggc 7313
||||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7455 tattgaggcgcaacagcatctgttcaactcacagtctggggatcaagcagctccaggc 7514
env 571 I E A Q Q H L L Q L T V W G I K Q L Q A

Query: 7314 aagaatcctggctgtggaaagataccataaaggatcaacagctcctgggatttgggttg 7373
||||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7515 aagaatcctggctgtggaaagataccataaaggatcaacagctcctgggnatttgggttg 7574
env 591 R I L A V E R Y L K D Q Q L L G I W G C

Query: 7374 ctctggaaaactcatttgaccactgtgtgccttggaatgtctgtggagtaataaattc 7433
||||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 7575 ctctggaaaactcatttgaccactgtgtgccttggaatgtctgtggagtaataaattc 7634
env 611 S G K L I C T T A V P W N A S W S N K S

Query: 7434 tctggAACAGATTGGAATAACATGACCTGGATGGAGTGGACAGAGAAATTAAACATT 7493
||||||| ||||| ||||| ||||| ||||| |||||

Art Unit: 1634

Sbjct: 7635 tctggAACAGATTGGAATAACATGACCTGGATGGAGTGGGACAGAGAAATTAAACAATTA 7694
env 631 L E Q I W N N M T W M E W D R E I N N Y

Query: 7494 cacaAGCTTAATACACTCCTTAATTGAAAGAACATCGAAAACCAGCAAGAAAAGAACATGAA 7553
|||||||

Sbjct: 7695 cacaAGCTTAATACATTCCCTTAATTGAAAGAACATCGAAAACCAGCAAGAAAAGAACATGAA 7754
env 651 T S L I H S L I E E S Q N Q Q E K N E Q

Query: 7554 agaATTATTGGAATTAGATAAATGGGCAAGTTGTGAAATTGGTTAACATAACAAATTG 7613
|||||||

Sbjct: 7755 agaATTATTGGAATTAGATAAATGGGCAAGTTGTGAAATTGGTTAACATAACAAATTG 7814
env 671 E L L E L D K W A S L W N W F N I T N W

Query: 7614 gctgtggtatataaaatttattcataatgatagtaggtggaggcttgtaggtttaaagaatagt 7673
|||||||

Sbjct: 7815 gctgtggtatataaaaatttattcataatgatagtaggtggaggcttgtaggtttaaagaatagt 7874
env 691 L W Y I K I F I M I V G G L V G L R I V

Query: 7674 ttttgctgtactttctgttagtgaatagatgttaggcaggatattcaccattatcgttca 7733
|||||||

Sbjct: 7875 ttttgctgtactttctatagtgaatagatgttaggcaggatattcaccattatcgttca 7934
env 711 F A V L S I V N R V R Q G Y S P L S F Q

Query: 7734 gaccCACCTCCAATCCCAGGGGACCCGACAGGCCGAAGGAATAGAAGAAGGTGG 7793
|||||||

Sbjct: 7935 gaccCACCTCCAACCCCGAGGGGACCCGACAGGCCGAAGGAATAGAAGAAGGTGG 7994
env 731 T H L P T P R G P D R P E G I E E E G G

Query: 7794 agagAGAGACAGACAGATCCATTGATTGAAACGGATCCTAGCACTTATCTGGGA 7853
|||||||

Sbjct: 7995 agagAGAGACAGACAGATCCATTGATTGAAACGGATCCTAGCACTTATCTGGGA 8054
env 751 E R D R D R S I R L V N G S L A L I W D

Query: 7854 cgatCTGCAGGAGCCTGTGCCTCTTCAGCTACCAACCGCTTAGAGAGACTTACTCTTGATTGT 7913
|||||||

Sbjct: 8055 cgatCTGCAGGAGCCTGTGCCTCTTCAGCTACCAACCGCTTAGAGAGACTTACTCTTGATTGT 8114
env 771 D L R S L C L F S Y H R L R D L L L I V

Query: 7914 AACGAGGATTGGAACTTCTGGACGCAGGGGGTGGGAAGCCCTCAAATATTGGTGGAA 7973
|||||||

Sbjct: 8115 AACGAGGATTGGAACTTCTGGACGCAGGGGGTGGGAAGCCCTCAAATATTGGTGGAA 8174
env 791 T R I V E L L G R R G W E A L K Y W W N

Query: 7974 TCTCCTACAGTATTGGAGTCAGGAGCTAAAGAACATGCTGTTAGCTGCTCAATGCCAC 8033
|||||||

Art Unit: 1634

Sbjct: 8175 tctcctacagtattggagtcaggaactaaagaatagtgctgttagcttgcataatgccac 8234
env 811 L L Q Y W S Q E L K N S A V S L L N A T

Query: 8034 agctatagcagtagctgagggacagatagggtatagaagtagtacaaggagcttntag 8093
||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8235 agccatagcagtagctgaggnacagatagggtatagaagtagtacaaggagcttntag 8294
env 831 A I A V A E G T D R V I E V V Q G A C R

Query: 8094 agctattcgccacatacac tagaagaataagacagggcttggaaaggatttgtataaga 8153
||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8295 agctattcgccacatacac tagaagaataagacagggcttggaaaggatttgtataaga 8354
orfF 1 D R A W K G F C Y K
env 851 A I R H I P R R I R Q G L E R I L L ^^^

Query: 8154 tgggtggcaagtggtaaaaaagtagtgtggatggctgtgttaaggaaagaatga 8213
||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8355 tgggtggcaagtggtaaaaaagtagtgtggatggctactgttaaggaaagaatga 8414
orfF 11 M G G K W S K S S V V G W P T V R E R M

Query: 8214 gacgagctgagccagcagcagatgggtggagcagcatctcgagacatggaaaaacatg 8273
||||| ||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8415 gacgagctgagccagcagcagatgggtggagcagcatctcgagacatggaaaaacatg 8474
orfF 31 R R A E P A A D G V G A A S R D L E K H

Query: 8274 gagcaatcacaagtagcaaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333
||||| ||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8475 gagcaatcacaagtagcaatacagcagctaccatgctgctgtgcctggctagaagcac 8534
orfF 51 G A I T S S N T A A T N A A C A W L E A

Query: 8334 aagaggaggaggaggtgggtttccagtcacacctcaggtaccttaagaccaatgactt 8393
||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8535 aagaggaggaggaggtgggtttccactcacacctcaggtaccttaagaccaatgactt 8594
orfF 71 Q E E E V G F P L T P Q V P L R P M T

Query: 8394 acaaggcagctgttagatcttagccactttaaaagaaaaggggggactggaaggctaa 8453
||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8595 acaaggcagctgttagatcttagccactttaaaagaaaaggggggactggaaggctaa 8654
orfF 91 Y K A A V D L S H F L K E K G G L E G L

Query: 8454 ttcaactccaaacgaagacaagatatcctgatctgtggatctaccacacacaaggctact 8513
||||| ||||| ||||| ||||| ||||| ||||| |||||

Sbjct: 8655 ttcaactccaaacgaagacaagatatcctgatctgtggatctaccacacacaaggctact 8714
orfF 111 I H S Q R R Q D I L D L W I Y H T Q G Y

Query: 8514 tccctgattagcagaactacacaccaggccaggatcagatatccactgaccttggat 8573

Art Unit: 1634

Sbjct: 8715 tccctgattggcagaactacacaccaggccaggggtcagatatccactgaccttggat 8774
orfF 131 F P D W Q N Y T P G P G V R Y P L T F G

Query: 8574 ggtgctacaagctagtaccagttgagccagagaagttagaagaagccaacaaggagaga 8633
Sbjct: 8775 ggtgctacaagctagtaccagttgagccagataaggtagaagaggccaataaaggagaga 8834
orfF 151 W C Y K L V P V E P D K V E E A N K G E

Query: 8634 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccggagagagaagtgt 8693
Sbjct: 8835 acaccagcttggttacaccctgtgagcctgcatggaatggatgaccctgagagagaagtgt 8894
orfF 171 N T S L L H P V S L H G M D D P E R E V

Query: 8694 tagagtggaggttgacagccgcctagcattcatcacatggcccgagagactgcattccgg 8753
Sbjct: 8895 tagagtggaggttgacagccgcctagcattcatcacgtggcccgagagactgcattccgg 8954
orfF 191 L E W R F D S R L A F H H V A R E L H P

Query: 8754 agtacttcaagaactgctgacatcgagcttgcataaaggactttccgctgggactttc 8813
Sbjct: 8955 agtacttcaagaactgctgacatcgagcttgcataaaggactttccgctgggactttc 9014
orfF 211 E Y F K N C ^^^

Query: 8814 cagggaggcgtggcctggcggactgggagtggtcgagccctcagatcctgcatataag 8873
Sbjct: 9015 cagggaggcgtggcctggcggactgggagtggtcgagccctcagatgctgcatataan 9074

Query: 8874 cagctgctttgcctgtactgggtctctctggtagaccagatctgagcctggagctc 8933
Sbjct: 9075 cagctgctttgcctgtactgggtctctctggtagaccagattgagcctggagctc 9134

Score = 2796 bits (1454), Expect = 0.0

Identities = 1477/1489 (99%)

Strand = Plus / Plus

It is noted that with regard to, for example, the sequence region between nucleotides 4487 and 5086 claimed in claim 11, there are two nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that

was significantly more advanced than that in 1984, when sequencing error rates were likely significantly higher. In the 599 nucleotide sequence which is the first sequence of claim 1, two errors would represent approximately a 0.3% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 35, 37, 39, 41, 43 and 45 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 35, 37, 39, 41, 43 and 45 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Chang because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the

labels of White to detect HIV as taught by Chang since White says that the method is broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

Response to Arguments

9. Applicant's arguments filed November 19, 2003 have been fully considered but they are not persuasive.

Applicant argues that the sequence of Chang was more carefully performed than the raw sequence analysis of Richterich, because the sequence was "polished". This refers to a term of art in which the sequence is repeatedly checked for accuracy. However, the issue in the current case is simply one of fact. Are the sequences the same or not? The examiner has read portions of John Crewdson's book "Science Fictions", which discusses the original studies on HIV in 1984. Crewdson quotes Wong-Staal, a coinventor on the Chang patent, as saying "that LAV and HTLV-3 are independent isolations of the same virus (see page 165)." Crewdson further notes "They had come from the same patient (see page 165)."

Further, Applicant specifically argues that Chang performed careful analysis. This is entirely belied and contradicted by Crewdson, who notes "The gene map of ARV, decoded by Paul Luciw and his California team, was a dead match for LAV, which meant Gallo's map was dead wrong (see page 173)." So contrary to Applicant's arguments, there was not significant care taken by Chang's group. At note s, on page 565, Crewdson writes, "The Gallo group had sequenced two clones of HTLV-3B. The first didn't appear to have the fifth gene but the second did. Or did it? Because HTLV-1

didn't have five genes, the prevailing opinion in Gallo's lab was that the AIDS virus didn't either and what looked like a fifth gene was an artifact." This further supports erroneous sequencing by Gallo, since at least once they failed to find an entire gene. This would be rather difficult to explain in a careful sequencing project.

So Applicant's entire argument rests on the supposition, without evidence, that the sequences were carefully performed.

Applicant's other argument is that Ratner resequences BH10. This is not correct. In reading Ratner's paper, there is no evidence that Ratner resequenced BH-10. Ratner simply compared a different clone to BH-10. At page 63, bottom of the page, Ratner states "The previously sequenced clone BH10 (28)", referring to reference 28, which is the original 1985 Nature paper and not some later resequencing. So, in fact, Ratner does NOT support applicant's position.

As a final point, it is noted that in this case, there is better evidence than is ordinarily available that the strains sequenced by the two different groups are, in fact, the same since it is clear that the LAI strain is common to both of these applications. There is express evidence, as discussed above, that the viruses were the same.

Since the evidence of record does not support Applicant's position, the rejections are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman
Primary Examiner
Art Unit 1634